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4 PUBLIC MEETING ON FINANCIAL TRANSPARENCY and
5 EFFICIENCY of the PRESCRIPTION DRUG USER FEE ACT,
6 BIOSIMILAR USER FEE ACT, and GENERIC USER FEE
7 AMENDMENTS
8
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10 June 7, 2019

11 9:00 a.m. - 11:30 a.m.

12 White Oak, Great Room

13 Section A (1503A)
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1 MS. ELLERBE: Good morning. My name is
2 Monica Ellerbe. I'm the Director of Business
3 Management Services in the Office of Operation,
4 Officer of Finance, Budget, and Acquisitions. I will
5 be your meeting facilitator today.

6 Welcome to the Financial Transparency and
7 Efficiency of the Prescription Drug User Fee Act,
8 Biosimilar User Fee Act, and Generic Drug User Fee
9 Amendments Public Meeting.

10 Dr. Patrizia Cavazzoni will have opening
11 comments and remarks and go through today's agenda.
12 Thank you.

13 DR. CAVAZZONI: Good morning, and welcome to
14 this public meeting. My name is Patrizia Cavazzoni.
15 I am the Deputy Director for Operations in the Center
16 for Drug Evaluation and Research.

17 As you're likely aware, under PDUFA VI, BsUFA
18 II, and GDUFA II, the FDA made several commitments to
19 enhance transparency in management of user fee
20 resources.

21 These commitments include developing a
22 resource capacity planning capability and modernizing

1 our time reporting, publishing five year financial
2 plans for each program, and contracting and
3 independent third party to conduct an evaluation of
4 program resource management during fiscal year 2018.

5 In addition to promote transparency, FDA
6 committed to hosting an annual public meeting in the
7 third quarter of each fiscal year beginning in 2019,
8 which is the meeting that brings us together today.

9 Together, these commitments represent a
10 significant amount of work that the Agency had
11 undertaken to further strengthen our ability to
12 efficiently utilize available program resources.

13 The resource capacity planning capability,
14 once fully established, will help the Agency utilize
15 data in a more systematic and proactive manner, to
16 help ensure the most efficient and effective
17 deployment of resources.

18 The publishing of the five year plans
19 provides us with an opportunity to communicate more
20 clearly to stakeholders the likely financial position
21 of each program over the current authorization cycle.
22 And the resource management evaluation, while

1 highlighting much of the progress that has been made
2 over the last few years, has identified additional
3 opportunity to refine some of our processes and
4 internal coordination.

5 We have a full agenda for today's meeting.
6 First, David Miller, Director of Division of User Fees
7 in the FDA's Office of Financial Management, will
8 present an overview of the five year plans for PDUFA,
9 BsUFA, and GDUFA.

10 Andy Kish, Director of CDER's Office of
11 Program and Strategic Analysis, and Josh Barton,
12 Director of the Resource Capacity Planning Team in
13 CDER, will provide an overview of the vision and
14 progress towards implementing the Resource Capacity
15 Planning Capability, and the Modernization of Time
16 Reporting.

17 Jim Taylor from the MITRE Grant Thornton
18 Health FFRDC Team will provide a summary of the
19 findings from their evaluation of the User Fee
20 Financial Program Management Evaluation.

21 And Jay Tyler, FDA's Chief Financial Officer
22 will provide the Agency's perspective and response to

1 the Financial Management Evaluation.

2 There will be time for public comments at the
3 end of the meeting. If you wish to sign up to speak
4 for the open public comment meeting, please do so at
5 the registration table.

6 There is also a public docket that is open
7 until July 8th to which the public can submit
8 comments.

9 A few brief housekeeping items; we will have
10 a ten minute break at approximately 10:20, and
11 bathrooms are down the hallway in the lobby and to the
12 left.

13 I will now turn over to David Miller to
14 provide an overview of the five year financial plans.

15 MR. MILLER: Thank you. Again, my name is
16 David Miller. I'm the Director of the Division of
17 User Fees within the Office of Financial Management,
18 which is a part of the Office of Financial, Budget and
19 Acquisitions, and I'm going to be going through a
20 general overview of the five year financial plans.

21 So, the first thing I'd like to do is just go
22 through some of the basics for the fee setting for the

1 Prescription Drug User Fee Program.

2 As you can see on the chart, the fee setting
3 goes through FY18 through FY22, the full timeframe for
4 PDUFA IV, and we start with the statutory base in
5 FY18, which is set in statute. This is the only
6 amount actually set in statute as a number; it is the
7 \$878,590 -- or I'm sorry -- \$878,590,000.

8 The next piece is the inflation adjustment,
9 which is an adjustment to maintain the purchasing
10 power of these user fee funds. This is a blend of CPI
11 and pay increases seen at the Agency.

12 Then you have the capacity planning
13 adjustment, which is intended to adjust the PDUFA
14 target revenue for changes in workload. Currently we
15 are utilizing an interim capacity planning adjustment
16 until the final methodology for the capacity planning
17 adjustment is completed, which may begin in FY21.

18 The interim adjustment is very similar to
19 what we were doing in PDUFA V, but there were some key
20 changes that were made. One of those key changes is
21 that it's focused more on the time invested in those
22 activities, instead of it being focused more on the

1 standard costs for each one of those activities.

2 So, what we're doing is we're adjusting for
3 workload on a weighted three year average over the
4 initial base period, which is also three years, and
5 that amount of change is applied to the amount from
6 the statutory base, and then inflation that's been
7 adjusted for that year.

8 The next line that we have is the additional
9 dollar amount set in statute. Those dollar amounts
10 are inflated independently on a yearly basis. Those
11 enhancement dollars are for FTE for the program, and
12 you can see that they're going to be rolled into the
13 base for the next fiscal year.

14 The Operating Reserve Adjustment is an
15 adjustment that's set forward to maintain no more than
16 14 weeks of operating and carryover balance. It was
17 utilized in the first year, coming from FY17 when the
18 balance was higher than that 14 weeks. That was a
19 reduction of roughly \$33.3 million. Those funds were
20 utilized in FY18 to, basically, make the total revenue
21 for that fiscal year whole.

22 The additional direct cost adjustment is the

1 last line of the fee setting methodology for PDUFA.
2 It was \$8.7 million in FY18, as you can see from the
3 table. That amount was for operating dollars for
4 specific contracts and is not rolled into the base in
5 the early basis. It is, actually, inflated from FY18
6 to FY22 independently.

7 An important thing to notice, for the
8 Operating Reserve Adjustment, is it has not been
9 utilized again since it was utilized in FY18, and the
10 Agency does not plan on needing to utilize it again
11 for the remainder of PDUFA IV.

12 The statute base for FY19 is a combination of
13 the statutory base for FY18, the inflation adjustment
14 for FY18, the Capacity Planning Adjustment for FY18,
15 and then the additional dollar amounts for FY18.
16 Those combined together equal the \$935.9.

17 Jumping to the next slide, I'm going to do a
18 quick overview of what you're looking at right now,
19 because I know it's a lot to take in.

20 The chart in front of you is three tables
21 combined. The top chart is the budgetary resources
22 available to the Agency. It is made up of target

1 revenue, cash collections, recoveries, and the
2 carryover balance, available carryover balance in the
3 previous year.

4 The important thing to note is we are also
5 utilizing for FY18 an estimated figure coming into the
6 year, and then what we ended up with. The target
7 revenue is not changed, but you can notice that the
8 cash collections do change, so we will projecting to
9 have \$911,346, and we collected, \$908,000.

10 The recovery line -- recoveries, just to give
11 you a general description of what they are, recoveries
12 are funding that were utilized for contracts in prior
13 years. Once that contract is complete, if there's any
14 dollars remaining on that contract belonging to the
15 program, they go back to the carryover balance in the
16 program, so we don't lose those funds.

17 The reason why the projection was zero
18 dollars in FY18, was we didn't have enough data to be
19 able to project what that number would actually be.

20 But you can see going forward, we do have
21 enough data at this point where we believe that we can
22 project it, and that number for FY19 is estimated to

1 be #10 million, and we've taken that \$10 million and
2 spread it out through FY22.

3 And the reason we're doing that is so we can
4 have a better estimate of what our budgetary resources
5 would be on a yearly basis, and at the same time have
6 a better prediction of what our carryover balance
7 would be at the end of the fiscal year.

8 The second table is on user fee obligations.
9 The user fee obligations are broken down by pay and
10 operating by center, and you can walk down through
11 that; do have an estimate and an actual for each one
12 of the centers. It also has a cost for rent and for
13 shared services.

14 Shared services at the Agency, at this point,
15 is also referred to as the work in capital fund. The
16 work in capital fund contains several offices within
17 the Agency that provide general services to all FDA
18 employees.

19 Just to give an example; my office of FBA is
20 a part of the work in capital fund, as well as human
21 resources, and facilities management.

22 The bottom chart is on carryover. So,

1 carryover provides you with several numbers. One is
2 the total carryover balance at the end of the year,
3 and also provides you with an unavailable balance.
4 That unavailable balance right now is made up of
5 funding from prior PDUFA authorizations that were not
6 appropriated; it's roughly \$79 million, along with a
7 set-aside amount that we hold for refunds.

8 The total comes out to \$83.8 million, which
9 provides us with a carry-around at the end of the year
10 that would be available for the following fiscal year
11 at the very bottom of the chart.

12 So, again, we are showing an actual and an
13 estimate here for FY18, and you can see that we
14 projected to have, at the very bottom, \$127.3 million
15 at the end of the year available, and we ended up with
16 \$125.3, so you're seeing that we're pretty accurate
17 with our projection of how much we thought we were
18 going to have going into the next fiscal year.

19 Another thing you'll notice is cash
20 collections. Cash collections were over 90 percent,
21 99 percent, accurate from what we had projected to
22 collection, to what we actually did collect.

1 Part of that is due to the impact that we've
2 had from the change in our fee structure. The fee
3 structure did change from PDUFA V to PDUFA VI, and one
4 of the big factors there is we were able to reduce the
5 amount of burden on the application fees coming into
6 the Agency by shifting it from 33 percent to 20
7 percent.

8 Applications are very volatile; they're very
9 volatile to predict, and relying on them less, in
10 terms of our revenue coming in, is a good thing, and
11 you're seeing the results.

12 Another thing that is really important to us
13 is the fact that the administration burden on coming
14 up with some of the older fees has been eliminated.
15 That would be the establishment fee, where there's a
16 lot of back and forth with industry trying to figure
17 out exactly how many establishments would be charged,
18 per company. It was very burdensome. We no longer have
19 that fee in PDUFA, so that burden had drawn down.

20 In addition to that, we also eliminated the
21 need to have a large cleanup billing after the fiscal
22 year ended.

1 So, after we had already finished FY18, for
2 example, we would be shifting into when are we going
3 to bill for the cleanup billing for FY18, and that's a
4 whole different billing process. So, we've eliminated
5 that, as well.

6 And as you can see, the results are we're
7 collecting 99 percent of what we believe that we're
8 going to.

9 The Agency wants to collect exactly what it
10 predicts; we don't want to collect less; we don't want
11 to collect more.

12 Another thing you're going to notice from
13 this chart is the carryover balance. The carryover
14 balance projected, or available to us in the beginning
15 of FY18, was \$232 million. That total has dropped to
16 what's available to us in FY19, is \$125 million.

17 That is a substantial drop in carryover from
18 one year to the next, and that can be attributed to
19 the \$33 million offset that we needed to do in FY18.
20 That drop, plus some additional targeted investments
21 in the PDUFA program, brought us down to an available
22 balance of \$125,372,000 in FY19.

1 You can see that that drop is going to
2 continue. The available balance in FY19 is \$125.3;
3 we're projecting to drop \$202.4 by the end of the
4 fiscal year. But then you're going to notice that
5 it's going to stabilize over the next three years.

6 So, we're projecting that we're going to be
7 dropping the carryover balance again to the \$104 --
8 I'm sorry -- the \$102.4, and then it will remain
9 relatively stable over the next three years, ending in
10 FY22 at \$104.7 million.

11 BsUFA. So, you can see BsUFA has some of the
12 same elements as PDUFA in this chart, from target
13 revenue. The base amount in statute is \$45 million.
14 There's an inflation adjustment, capacity planning
15 adjustment, and operating reserve adjustment, and a
16 normal, regular, adjustment for FY18, which is being
17 utilized to enable us to reduce our carryover balance
18 into the future years.

19 Again, the program, in BsUFA II, with a large
20 carryover balance, and we did commit to reducing that
21 balance over time below the 21 weeks of operating,
22 which is set in statute, through the operating

1 reserve.

2 One of the big things to note for BsUFA, is
3 it's still a relatively new program, and it's
4 extremely volatile. This is the first authorization
5 for the program that it has its own fee structure,
6 with fees mapped out in statute that are not attached
7 to a fee related to the PDUFA program.

8 So, in BsUFA I, you were paying a percent --
9 your fee was a percentage of the PDUFA fee, and now
10 BsUFA is completely independent of itself.

11 One of the important things, also to note in
12 the program, is there's not a lot of fluctuation in
13 inflation capacity planning. What you're seeing here
14 is a normal inflation adjustment going from 18 to 22.
15 Capacity planning is in the same boat as PDUFA. We're
16 waiting for that methodology to be developed and
17 approved, and once that happens, we could,
18 potentially, have a Capacity Planning Adjustment in
19 FY21.

20 So, I'm glad I did the walkthrough on the
21 budgetary resource obligations and carryover; you're
22 going to see this table one more time after this.

1 The biggest things to note for BsUFA, again,
2 is that the program is extremely volatile, and you're
3 going to see that several times over this chart. The
4 first being in its cash collections.

5 Cash collections for BsUFA was projected and
6 targeted to be \$40,214,000. We ended the year with
7 \$29,238,601. That is an \$11 million drop in
8 collections. It's a gigantic loss in revenue, and so
9 as a result, you're going to be able to see at the
10 bottom, that the carryover balance dropped
11 significantly.

12 So, we planned on spending \$40,465,000, we
13 spent \$40,279,000; we did a pretty good job on what we
14 said we were going to do, but nonetheless, the program
15 didn't collect as much as we were hoping, so the
16 carryover available at the end of the year, which we
17 were projecting, was around \$48 million, and we ended
18 up carrying over \$38 million.

19 So, again, the big issue with BsUFA is it's
20 extremely volatile, it does rely on several fee bands,
21 but one of them is applications and you can see from
22 the table, and the notes on the side, that the fee

1 applications were 56 percent lower than anticipated.
2 And the Agency hopes that that volume will kick up,
3 but it's still a very volatile program and cash
4 collections will vary from year to year.

5 Another thing about the volatility of the
6 program is the impact that the spendature (ph) has on
7 the program. BsUFA needs a conservative spending
8 approach, and it needs a conservative spending
9 approach not only because collections vary from year
10 to year, but also because we're committed to spending
11 \$20 million in non-user fee budget appropriations
12 every year, plus an inflation factor that's set forth
13 in the statute.

14 I have the numbers in here for FY18; that
15 trigger was \$21,711,380. We cleared that trigger by
16 \$600,000 last year. So, \$600,000 is only three
17 percent.

18 So, this is all dictated by the program time
19 reporting. So, how much time is being spent on the
20 BsUFA program, in relation to how much money is being
21 spent at the centers, and you can see that that is
22 just not a very large gap between the trigger itself.

1 Now, BSUFA does have a threshold that we can
2 miss that trigger by; it's 15 percent. So, the three
3 percent cleared from the actual trigger, which is
4 where we want to be above. We do have the ability to
5 be below it by roughly \$3.9 million.

6 So, we could miss the trigger; we could have
7 been lower by 18 percent, and still have made the
8 trigger, but that is extremely important to have in
9 the program, if we're going to be able to move forward
10 and meet that trigger on a yearly basis, considering
11 the volatility.

12 So, the next program, you'll notice, is a
13 little bit more straightforward. This is the Generic
14 Drugs Program. It doesn't have a Capacity Planning
15 Adjustment. There's no Operating Reserve Adjustment.

16 Now, the Agency does love to hold between
17 eight to ten weeks of carryover to mitigate risks.
18 Those risks would include risk of government shutdown,
19 or enhancements that need to happen in the program, to
20 have some dollars available. Or, you know, cash
21 collections not coming in where we need them to be.

22 But we don't have an adjustment here, which

1 means we can hold over the eight to ten weeks over the
2 14 weeks, if need be. The base amount is set in
3 statute, was \$493,600,000 and you can see that that's
4 inflated on a yearly basis just by inflation.

5 Now, one important thing to note here on the
6 chart is cash collections. We did collect over 99
7 percent of the GDUFA funding that we -- actually, more
8 than 100 percent. It was just over 100 percent. So,
9 it's \$493.6 is what we wanted to collect; we collected
10 \$493.6. \$55,000 -- \$56,000 over our target revenue.
11 It was extremely close. It was an excellent job, by
12 the Agency, of being able to predict its collections
13 for the year and estimating the fee bands.

14 There is some volatility in those fee bands,
15 but those fees are relatively new, and refinements
16 will be made.

17 Like I said before, we don't have an
18 operating reserve in GDUFA, but we do maintain an
19 eight to ten week carryover balance. That balance,
20 you'll see from this chart, is actually a little
21 higher than the eight to ten weeks; it's closer to 14
22 weeks and one of the reasons for that is the estimates

1 for obligations in FY19 have been lowered from last
2 year.

3 They were lowered from last year because
4 we've having some issues with hiring. You'll see from
5 the chart. You can have -- we have hiring challenges
6 in FY19, and it's expected -- we're still expected to
7 decrease this balance over the next four years, but
8 that is impacting the total of the program.

9 That was it. Thank you.

10 MR. KISH: All right. I know it's always
11 good to start the morning with consolidated financial
12 statements. If you need more coffee, I don't blame
13 you, but thank you for David, for going over it.

14 We're all very familiar with it. I know it
15 might take some time to get familiar with those
16 statements, so please do review them, and the five-
17 year plans that are now out publicly.

18 I'm going to briefly introduce Capacity
19 Planning. Josh, to my left, is really going to dive
20 into it and give you, not the most detailed overview,
21 because it is a very detailed topic, but hopefully, a
22 deep enough dive to help understand what that

1 commitment is, and where we are with implementing it.

2 So, this really came out of PDUFA
3 negotiations, and then it continued over to BsUFA and
4 GDUFA.

5 When we were discussing Modernized Time
6 Reporting and Capacity Planning, the negotiations, the
7 Agency really saw a lot of value in this capability
8 and bringing it into the Agency.

9 It primarily comes out of R&D operations in
10 the pharmaceutical industry, and it -- at its
11 simplest, it's using data to figure out what resources
12 you need, before you need them, to complete a
13 performance of certain unit of work, in a certain
14 period of time.

15 We committed to three major commitments
16 across the three programs. One is to publish an
17 implementation plan for Modernized Time Reporting
18 Capacity Planning. That is completed. It was out
19 last spring.

20 If you haven't read it yet, it's on the
21 website. Feel free to read it. It's a fairly good
22 read. Maybe don't read it right before you go to bed.

1 We also committed to staffing our Capacity
2 Planning Team to implement and manage the system. I
3 would say, we've got team established in CDER and in
4 Headquarters. We still need to add folks to that
5 team, and bring in more capability, but we do have it
6 in place, and we're continuing to build.

7 Another commitment that Josh will dive into a
8 bit more, is around conducting a third-party
9 assessment to recommend a new methodology to adjust
10 fee revenue amounts. That's based on capacity needs.
11 That applies only to PDUFA and BsUFA.

12 That evaluation will be completed around next
13 spring or published around next spring. Public
14 comment, once we receive public comment, we do have
15 the capability to add a new revenue adjuster, capacity
16 adjuster, to PDUFA and BsUFA. That would be in time
17 for setting fees for '21.

18 So, we spent a fair amount of time planning
19 how to implement Capacity Planning. We actually
20 started in 2016 on this work, in terms of planning.

21 At its simplest, the vision we've established
22 is to maximize our operation to deliver on our public

1 health mission. I'll go through this a bit slowly
2 because it's a lot of words, but we went through a
3 consensus process to come up with this across all
4 medical products, to develop a unified and trusted
5 resource management capability to foster innovation,
6 maximize our operational performance, facilitating the
7 flow of products to patients first in the world, in
8 order to protect and promote public health, and meet
9 our commitments to the American public.

10 So, it's a mouthful. If you get asked about
11 the vision of Capacity Planning, probably the top's
12 the easiest; FDA is trying to maximize operations to
13 deliver on its mission.

14 So, on that I'll hand it over to Josh. He's
15 going to do a deeper dive into Capacity Planning and
16 where we are in implementation.

17 MR. BARTON: Thank you, and testimony. As
18 Andy mentioned, we've been really working on this
19 since 2016. So, I really appreciate your interest
20 today, in joining us, so we can talk through all the
21 work that we've been doing here, and the work to come.

22 So, Andy mentioned the plan that we published

1 last spring, at the end of March, as well as that
2 vision statement. In the text of the commitment for
3 that plan, it required us to bring third-party
4 consultant contractor to help advise us on how we
5 design the implementation plan for this capability.

6 So, we were working with Price Waterhouse
7 Cooper's PWC, the R&D Advisory Services, and that's a
8 practice that typically works with R&D operations
9 within the bio-pharmaceutical sector.

10 So, we were working with them. That vision
11 statement that Andy just read was part of the
12 consensus process that we organized across the Agency,
13 as part of that planning effort with PWC.

14 And really, the logic of bringing in, you
15 know, a third-party expert in this field, is really to
16 help the Agency so that we can benefit from
17 established best practices in this field, and we're
18 not building this -- making this up on our own.

19 But, obviously, the way that our human
20 medical product programs work, is -- the operating
21 paradigm is a little bit different, obviously, than
22 the way industry works. And so, we've adapted this

1 Resource Capacity Planning vision to really match our
2 paradigm.

3 So, what's up on the screen here, this is
4 perhaps over-simplistic but hopefully, really
5 emphasizes kind of the key difference between the way
6 industry and FDA would work in this space.

7 So, in -- you know, maybe again, an over-
8 simplistic, sort of industry model, if there's an idea
9 for a new project, that might go through a process of
10 reviewing a strategy, if that project fits into the
11 strategy and/or priorities of the organization. If
12 so, there might then be a review of, do we have the
13 people with the volume and the types of skills that we
14 need to deliver on this project? And if yes, great,
15 if no, you might be able to find additional resources,
16 i.e., bringing on contract resources, you could look
17 at re-prioritizing other work within the portfolio, or
18 perhaps delaying the initiation of the project until
19 the appropriate resources are freed up.

20 Within FDA, when we're talking about our UFA
21 (ph) programs and the performance goals that we have
22 around those programs, when we get a new submission

1 that if there's a performance goal, we get that done
2 within the timeframe that's required, with the
3 resources we have available.

4 So, if we get -- if we were to get a large
5 bellist (ph) of NDA's today, they're going to get
6 reviewed by the staff what are here today.

7 So, what that means, in order for us to
8 really be able to adjust our staffing levels to meet
9 the resource demand, with enough lead time, we need to
10 have a forward looking proactive capability, that can
11 really begin to understand where work is headed, so
12 that we can identify the resources before we actually
13 need them, so we can get them in place when we do need
14 them.

15 So, how do we plan on doing that? Again,
16 this is very high level, and perhaps simplistic, but
17 hopefully pulls together the main concepts.

18 So, we have a couple of different
19 capabilities that are in play here. The first is our
20 time reporting. So, the commitment letter talks about
21 our Modernized Time Reporting. We've rebranded our
22 Time Reporting as Insight Time Reporting. It's really

1 about providing insight into our resource needs. So,
2 you know, the branding's a little bit better than
3 Modernized Time Reporting.

4 But the Insight Time Reporting, that provides
5 us, you know, we're now doing 52 weeks a year of time
6 reporting, where up until -- you know, we had
7 historically been doing eight week -- a total of eight
8 week samples across the year.

9 So, we have a much -- we are working towards
10 collecting a much greater volume of time reporting
11 data and have a much better picture of our -- how our
12 operations are being invested.

13 But that provides us much better data on
14 level of effort for different types of work. But
15 that's also combined with our workload forecasting
16 capability.

17 And when we say workload forecasting, we're
18 really talking about developing advanced analytics to
19 really model what's happening in medical product
20 development, and translate that into forecasts of
21 likely incoming work, i.e., regulatory submissions.

22 That is then pulled together to translate

1 likely regulatory submissions, into resource need.
2 And this can be used in a number of different ways,
3 including balancing available resources today, being
4 able to adjust the revenue for PDUFA and BsUFA, which
5 Andy talked about a little bit, being able to develop
6 more proactive hiring plans, and help to better inform
7 our financial forecasting, and how we are executing
8 our spending triggers, which David talked about a
9 little bit, throughout the course of a fiscal year.

10 So, how are we going to do this? And this is
11 from the report we published. So, if you're read that
12 report, this might look familiar.

13 We've established very high level five phases
14 of implementing this full capability, and we're still
15 very much in phase one, which is really building the
16 foundation.

17 So, this phase one includes our 100 percent
18 time reporting, developing our initial workload and
19 resource forecasting capabilities, and we're very much
20 progressing through this.

21 Our next phase, which we're beginning to
22 engage in, is really developing the support model and

1 the organization, as well as the business processes to
2 really integrate these capabilities into decision
3 making within the organization.

4 Once that is accomplished, phase three is
5 really about doing the close loop planning. So, this
6 is where we'd have our forecast of our resource needs,
7 we'd be able to track our actuals to those forecasted
8 needs, and we'd be able to refine our forecast, as
9 well as begin to make informed decisions about how to
10 adjust, if and as necessary, our resource deployment.

11 From there we have this planned business case
12 refinement and stage gate review. So, these first
13 three phases are really taking us through the current
14 authorization period, and -- but we want to keep this
15 idea of this longer term vision, this longer term
16 integration, as something that is possible.

17 And once we've completed, gotten through the
18 three phases of the initial implementation, you know,
19 the organization can consider the cost and benefits of
20 continuing to further integrate with our project
21 management and our corporate analytics and reporting
22 capabilities.

1 In working with PWC, you know, one of the
2 things that they communicates is, if you're going into
3 an organization that has, sort of, a green field of
4 systems and capabilities, you'd really first focus on
5 developing a project management capability, and then
6 you'd build these time reporting and resource planning
7 capabilities on top of that.

8 But because we really have -- we have a
9 variety of project management workflow and management
10 tools in place, that are being updated, we've really
11 flipped this to focus on the capabilities we committed
12 to establishing within the authorization period, the
13 Time Reporting and the Capacity Planning, but we
14 really wanted to keep the vision of the longer term
15 integration as something that is possible in the
16 longer term.

17 So, this next slide is also from the -- our
18 published plan. I wanted to just dive a little bit
19 more in-depth about what we would accomplish and the
20 benefits we would have at certain phases within that
21 five phased plan.

22 So, at the completion of phase three we would

1 have -- we would expect to have the ability to
2 forecast our user fee program cost and be able to
3 track our actuals to those costs.

4 This would be a little bit more of a macro
5 level, looking programmatically across the board, and
6 we built on -- we see here the operational backbone.
7 This would be integrating data from across the
8 enterprise, as necessary, to be able to inform these
9 projections.

10 So, we'd have a more systematic and
11 consistent Resource Capacity analysis across the
12 organization, we'd have our forecasts that would be --
13 resource forecasts that would be more integrated with
14 our financial planning processes. We'd have a more
15 emerging proactive ability to identify resource gaps,
16 and develop tactics to address those gaps, and we'd
17 have this emerging holistic and more comprehensive
18 view of our resource needs across our book of work
19 within the organization.

20 Then phase five, this would be the full
21 implementation of the long term capability, should we
22 decide to continue towards that full implementation.

1 This would -- you'll see here, the operational
2 backbone here is really based on this integrated
3 project management data.

4 So, the idea here, the real, sort of,
5 enterprise difference here is that our project
6 management capability would be closely integrated,
7 fully integrated, with our time reporting and our
8 capacity planning capabilities.

9 What that would provide us would be a much
10 more microlevel understanding of resource utilization
11 and have that closely integrated with workflow
12 processes.

13 So, you'd be able to see, at a much more
14 granular level, any bottlenecks within processes, and
15 be able to identify opportunities for continual
16 improvement around our processes.

17 So, this would provide a much more
18 authoritative source of planning data, provide key
19 technical resource capacity information to frontline
20 management, a much more robust and flexible portfolio
21 of reporting, based on a holistic book of work, and
22 provide improved tools to support operational

1 strategies and prioritization of work, and an ability
2 to deliver authoritative portfolio and Resource
3 Capacity Planning data as needed across all levels of
4 the organization to support strategic and operational
5 decision making.

6 Where we are today; like I said, we've been
7 doing a lot of work since -- for almost three years,
8 at this point.

9 This is organized broadly in four different
10 areas. The first being the initial planning effort to
11 get -- you know, get the ball rolling in this
12 capability development, and that was really organized
13 around the plan that was published last March.

14 We've had a lot of work around the Time
15 Reporting Implementation. CBER implemented full time
16 reporting beginning in FY18, and CDER just completed
17 the Insight Time Reporting implementation -- we had
18 this ready to go in January, but due circumstances
19 beyond our control, that was delayed a little bit, and
20 so we completed between March and April the Insight
21 Time Reporting Implementation across CDER. So, now
22 all CDER offices are doing full time reporting, from

1 here on out.

2 All that Time Reporting work required a lot
3 of work; we spent about a year taking our existing
4 Time Reporting categories and really reviewing what
5 would make sense in the new paradigm and doing a lot
6 of the technical development.

7 So, the Insight Time Reporting tool, which is
8 intended to be used across the enterprise, within the
9 FDA, as needed, is developed on a Sales Force
10 platform. So, this is an application we configured to
11 meet our needs.

12 We did a lot of work thinking about, you
13 know, can we use something off the shelf for time
14 reporting? And we really thought it made a lot of
15 sense to be able to have a lot of control over the
16 interface and the data model, so that we can really
17 make sure it's adaptable and flexible to meet our Time
18 Reporting requirements.

19 So, that was actually one of the first agile
20 development projects that has occurred in the FDA, and
21 so that's been working really well for us.

22 We've also been focused on developing the

1 broader RCP capability, and really -- this has really
2 been a large focus since about the September
3 timeframe. We've established another engagement
4 effort with PWC and established a number of different
5 workstreams around the various capabilities that need
6 to come together to support the broader RCP
7 capability.

8 We, of course, have also been working on the
9 organizational development, bringing the staff we need
10 to implement this capability, and you know, that's
11 always an ongoing effort.

12 We also have the Adjustment Methodology
13 Study, which I'll talk about a little bit as well.

14 In terms of how we're running this
15 internally, this is the program structure we've
16 established within the Agency. We have a steering
17 committee, which is connected to our User Fee
18 Governance Committee, and establishes the broad vision
19 and reviews the direction of the program.

20 We have a core team, which really organizes
21 and runs the program. We have extended teams within
22 certain parts of the organization; we have focused in

1 CDER, because we've really focused on the Insight Time
2 Reporting Implementation over the last year, and we
3 have a Cross center Extended Team, and that's really
4 to keep stakeholders from across -- you know, outside
5 of CDER as part of the program, as well, to help
6 prepare them for their own Time Reporting
7 Implementations.

8 We have a set of delivery teams, which are
9 focused on the various areas, including the Time
10 Reporting, the Workload Forecasting, which I'm going
11 to talk about a little bit in the next couple of
12 slides.

13 The Resource Forecasting, which again, is
14 translating the Workload Forecasts into the resource
15 needs.

16 We also have a Training, Communications, and
17 Change Management Team, which supports all three of
18 those delivery teams, as well as a Business and
19 Technical Integration Team, which helps really make
20 sure all the technology is working.

21 So that, very much, has been focused,
22 initially, on the Insight Time Reporting, but as we

1 move towards the broader Resource Capacity Planning
2 and analytical capabilities, and bringing that
3 together to support the organization, there will be a
4 lot of additional technical integrations that will
5 need to occur to implement that full capability.

6 So, I want to talk a little bit more about
7 our Workload Forecasting. This is a pretty
8 interesting aspect of our work, in my opinion. So, I
9 alluded to this a little bit already, but this is,
10 really, understanding where our work is headed.

11 So, what we're doing, in a sense, is to --
12 using internal FDA data, as well as relevant external
13 data, and -- working to develop models and
14 understanding what's happening with drug development,
15 so we can develop predictive analytics around the
16 likely regulatory submissions we expect to receive.

17 So, we have a wealth of internal data, which
18 has been really helpful in this regard. A lot of it
19 tends to be unstructured, so there's a lot of work, in
20 terms of, you know, identifying relevant text within
21 various documents, and pulling that together in a
22 systematic way. That can then be used for analysis.

1 We're looking at other data sources,
2 including things like ClinicalTrials.gov, as well as
3 other commercially available external data sources
4 that can help supplement the picture we can develop
5 from internal data.

6 So, we have laid out here timeframes for
7 initial model development. Before I say anything
8 more, I want to highlight initial model development.

9 So, like I talked about in the slide with the
10 five phases, we're still really very much building a
11 foundation here, and what we really want to do is to
12 focus -- we're, at this point, developing initial
13 predictive analytics.

14 We're exploring the data, we're exploring
15 methodologies that are helpful to -- and predictive,
16 and really focusing on some of these more -- some of
17 these more major submission types, like NDA's -- the
18 original NDA/BLA's, the number of IND's we're
19 receiving, the number of supplements receiving, the
20 number of NDA's, originals and supplements we're
21 receiving.

22 Of course, this is only -- this is a

1 significant aspect of our work, but this is not,
2 obviously, the full portfolio of the work that we do.

3 But we're really very much trying to develop
4 this foundation, focus initially here, and these
5 models will evolve over time. We see this as being a
6 very iterative process, and as we learn more about,
7 you know, effective methodologies, as well as we get
8 more data from the actuals, the predictive analytics
9 here will evolve and you know, this will be an ongoing
10 process. This is always something that will be
11 managed and iterated upon and improved upon over time.

12 We've laid this out in a couple of waves over
13 the next year, or so. The first focusing really on
14 the NDA and BLA originals, as well as their
15 resubmissions, and then the new IND's we may receive,
16 as well as the workload generating active IND's that
17 the Agency is overseeing, and we're making a lot of
18 progress through that wave.

19 Wave number two is focused more around the
20 efficacy supplements, manufacturing supplements,
21 labeling supplements, as well as the formal industry
22 meetings, which have been increasing significantly

1 over the last few years.

2 Then wave three is really looking -- you
3 know, taking a first look at the -- some of the GDUFA
4 relevant work around the ANDA's, both the originals
5 and the supplements.

6 So, in essence, we're really trying to model
7 a large portion of activity in the pharmaceutical
8 industry; we're translating that into how that impact
9 the Agency.

10 What I have here on this slide; this is a
11 very preliminary analysis, and is really only here to
12 help, you know, illustrate, sort of, the -- some of
13 the concepts here around Workload Forecasting.

14 But the example that we're showing is that by
15 looking at activity within IND phase, the hypothesis
16 is that we can use that to then predict NDA or BLA
17 submission.

18 So, in the example here, which again is very
19 preliminary, and still very much a work in progress,
20 we've used a survival random forest model. This is a
21 machine learning technique, which involves developing
22 a large number of covariates and pulling together a

1 large amount of data and utilizing a machine learning
2 algorithm to develop predictions.

3 But what you see here is that looking at --
4 so there's basically two examples. In the first one
5 we have a IND that had an end of phase two meeting
6 between three and four years ago. It's had a
7 proprietary name request; something related to a
8 proprietary name request within six to twelve months
9 prior, and it's had some type of meeting request six
10 to twelve months prior.

11 So, in those -- in an IND, with those types
12 of characteristics, in this very preliminary and
13 conceptual model, that would have -- according to the
14 initial preliminary results, would have roughly about
15 a 60 percent chance of becoming an original NDA or BLA
16 within about one and a half years.

17 As opposed to the example on the right; an
18 IND what does not have any of those three things, does
19 not have a phase two meeting, does not have anything
20 related to proprietary name request, or a meeting
21 request. In the same timeframe, about 1.5 years out,
22 has a less than one percent change of becoming an

1 original NDA or BLA.

2 Of note, if you're comparing these graphs,
3 the scale on the left is different. So, that -- just
4 for your awareness. Visually, it's really one percent
5 on the right and it's 60 percent on the left.

6 Again, this is just a very simple and early
7 example of the type of work we're looking to do to
8 develop these predictive analytics. The survival
9 random forest is, like I talked about, is a machine
10 learning algorithm. We're looking at the application
11 of other types of machine learning algorithms, as
12 well, as traditional statistical techniques, and as
13 well as, you know, where appropriate, using other time
14 series or moving averages, where appropriate.

15 What we're really trying to do is not to
16 limit ourselves, preemptively, to any specific
17 techniques, but when we approach a problem, and
18 approach a need to develop a predictive model, really
19 keep everything in play, and then see which types of
20 techniques work -- seem to develop the best and most
21 accurate types predictive forecasts.

22 So, again, this is just an example, but it's

1 -- you know, hopefully helps to make this a little bit
2 more real.

3 I want to talk a little bit about next steps,
4 in terms of adjustment methodology. So, this is a fee
5 adjustment that could be applied to PDUFA and BsUFA.

6 So, as David talked about, PDUFA has an
7 interim Capacity Planning Adjustment Methodology,
8 which is really an extension of the -- what had been
9 the PDUFA Workload Adjuster, that had existed prior to
10 PDUFA VI. BsUFA II does not have, currently, any sort
11 of adjustment to the fees for capacity needs.

12 But what is shown here is the language from
13 the PDUFA section of the statute that outlines how we
14 can go about implementing a new Capacity Planning
15 Adjustment methodology, and this is similar for BsUFA.
16 But that involves conducting another third-party
17 evaluation, and this evaluation would be specifically
18 focused on what should the Fee Adjustment methodology
19 look like and developing ideas and recommendations
20 around that. Options or recommendations.

21 That evaluation must be published for public
22 comment, and then once that's done, once that's

1 published for public comment, once FDA reviews public
2 comment, we do have the ability to implement a new
3 adjustment methodology.

4 So, the -- we had planned an expect to have
5 that third-party evaluation to start early in the next
6 fiscal year, so of course, our fiscal year start in
7 October. We would expect to have that published for
8 public comment around the springtime. So, roughly,
9 around March of next year, 2020, in order to meet that
10 -- the possibility of the FY21 adjustment.

11 So, if you're familiar with how our fees our
12 set; we publish the fee notices at the beginning of
13 August, so you know, we'd be working back from there
14 if -- you know, in terms of implementing a new
15 adjustment methodology.

16 So, that's the process. Just to highlight a
17 little bit; so, this is -- summarizing a little bit,
18 some of the current state of the PDUFA Capacity
19 Planning Adjustment that is used today, which as I
20 mentioned, is really an outgrowth of the PDUFA
21 Workload Adjuster, prior to PDUFA VI.

22 The background here is a PDUFA Workload

1 Adjuster is something that was developed beginning
2 back in 2003 with PDUFA III. There's been -- some
3 adjustments have been made over the years, but it's
4 really intended to -- it was always intended to adjust
5 the top line total target revenue in a fiscal year to
6 meet our trends and workload.

7 It does present some structural adjustments.
8 So, if you're familiar with it, you'll know it's based
9 on three year averages. So, it's -- in instances
10 where we have growth, it's a lagging indicator. So,
11 it's -- if there's trends, whether they're up or down,
12 it's going to -- you know, it's going to take time for
13 those numbers to catch up.

14 So, it's a lagging indicator, which means it
15 compensates us for increases that occurred in the
16 past. It's based on submission counts and it's -- the
17 timing is higher -- is compounded by hiring
18 timeframes.

19 So, based on submission counts -- it's simply
20 looking at things like the number of NDA's and BLA's
21 submitted over the -- you know, the previous three
22 year period, versus the current three year period.

1 So, it doesn't translate -- so, if I were to
2 say, hypothetically, you know, we have ten percent
3 more NDA's, it doesn't translate that in terms of
4 resource need. It doesn't translate that into, you
5 know, ten percent more NDA's means X number of medical
6 officers, or Y number of project managers, etcetera.

7 The timing compounded by hiring frames, since
8 it's a lagging indicator, and if you have a growth,
9 you know, a period of growth, it does take the Agency
10 time to hire and to train regulatory review staff, so
11 you know, when you're in a growth period, using the
12 adjustment as is to provide the resources you need,
13 it's -- there's always going to be a -- you know, a
14 gap that we would be struggling to catch up to.

15 So, there's kind of a structural issue with
16 the way that the adjustment currently works, which is
17 why we see a lot of value in developing a more forward
18 looking revenue setting methodology.

19 Of course, this is based around forecasts.
20 So, there's always uncertainty when you're developing
21 a forecast, and we'd have to, you know, be very
22 thoughtful about how we're adjusting within, you know,

1 any sort of forecast range.

2 But a future state adjustment, you know,
3 would -- it would be very helpful for it to be a
4 forward looking adjustment. It could, with our
5 Resource Capacity Planning capability, help compensate
6 us for likely sustained increases, so we don't want to
7 staff to, you know, temporary peaks or spikes in
8 submissions, but really -- because we have a very,
9 sort of, fixed labor pool, we want -- really need to
10 plan to, you know -- the sustained workload levels.

11 With our Resource Capacity Planning
12 capability, we'd be able to translate that submission
13 activity into likely sustained resource demand. So,
14 like I said, instead of just ten percent more NDA's,
15 what does that mean in terms of the number of medical
16 officers, etcetera.

17 And this could provide us with the
18 opportunity to optimize the timing of our planning for
19 resources to account for hiring and training
20 timeframe, so we can get folks ready to do the work,
21 you know, when the work is coming in.

22 So, this will really be elicited through that

1 third-party study that we talked about, but these are
2 some initial ideas about some of the opportunities
3 around a new more forwarding looking fee revenue
4 setting methodology.

5 So, the graphs on the right, if you can read
6 that, that's really -- what that's trying to do is
7 really say, okay, if -- you know, these are the number
8 of -- in this example -- active commercial IND's we're
9 expecting, what does that mean in terms of our RPM's
10 in Office A, or medical officers in Office B?

11 And with that, I think that's my material, so
12 I'm going to -- but I, again, very much appreciate
13 your interest and your time here with us today.
14 Thanks.

15 MS. ELLERBE: Thank you, Josh. Given the
16 current pace of the meeting and in an interest of
17 saving time, we would like to forego the ten minute
18 break and continue on with the presentations. Great.

19 Jim Taylor, thank you.

20 MR. TAYLOR: Good morning. Now, there's a
21 danger of skipping this break; the agenda was very
22 carefully construed so that you'd have a chance to get

1 coffee, because now the accountants are going to start
2 talking. So, I hope you have enough coffee in you to
3 continue to get this going.

4 My name is Jim Taylor and I'm a Managing
5 Director with Grant Thornton, and I'm really pleased
6 to be with you here today representing the FFRDC, the
7 Health FFRDC, the MITRE GT Team, and well as to
8 present to you our just released Financial Management
9 Evaluation of the Human Drug User Fees for FDA.

10 Before I talk about the conclusions of the
11 study, let's maybe take a step back and give you a
12 little bit of background.

13 The seamless alliance to modernize
14 healthcare, the Health FFRDC, is the first federally
15 funded research and development center dedicated to
16 strengthening the nation's healthcare system. It's
17 sponsored by the Centers for Medicare, Medicaid
18 Services, CMS, and the other divisions of the
19 Department of Health and Human Services.

20 The MITRE as an objective, a not for profit
21 organization, operates the Health FFRDC in partnership
22 with CMS to implement innovative ideas to solve our

1 nation's toughest health problems.

2 The Health FFRDC is composed of an alliance
3 of partners and members who are committed to providing
4 conflict free objective expertise to HHS and its
5 divisions, and as one of those partners, Grant
6 Thornton is really proud that we were asked to
7 participate in this and bring our expertise in federal
8 and commercial financial management, and user fee
9 evaluation, to the team.

10 Now, FDA collects over \$1.4 billion in human
11 drug user fees annually. The Prescription Drug User
12 Fee Act authorized FDA to start charging user fees
13 from sponsors of new drug products back in 1992, and
14 the subsequent new user fee programs, including GDUFA
15 and BsUFA, have increased financial management
16 complexity, which I think is pretty obvious from the
17 prior presentations.

18 Through authorization agreements for
19 Prescription Drug User Fee Act for the three programs,
20 included FDA's commitment to engage in independent
21 third-party to conduct an evaluation of its financial
22 management practices, and as a result, FDA asked the

1 Healthcare FFRDC to develop a comprehensive evaluation
2 focused on five specific areas of FDA's financial
3 management capability for the three programs during
4 fiscal year 2018, and to provide recommendations based
5 on best practices to help ensure that FDA's User Fee
6 Financial Management capabilities are consistent with
7 the best practices in the federal government.

8 So, the five areas that we were asked to
9 specifically look at, included the resource planning
10 and request allocation and user fee administration,
11 administration of user fee programs, oversight and
12 governance, technical capabilities, and the user fee
13 estimating methodology.

14 So, our full report has been posted online by
15 the FDA, and I feel compelled to tell you that the
16 next slide is actually the spoiler slide. So, for
17 those of you who are going to go and are anxious to
18 read that full report, I'm about to give you the
19 conclusion, and after spending the whole last season
20 of Game of Thrones with my kids, I'm worried about
21 spoilers, and I want to make sure that you're very
22 clear on this before you go read this report.

1 What we did conclude is that FDA's financial
2 management maturity is appropriate for the governance
3 management, and the oversight of its Human Drug User
4 Fee programs. We concluded that FDA is fully
5 compliant with financial management requirements, and
6 that they're within two percent -- it think David had
7 one percent -- I think it's a timing thing -- of
8 target revenue across all Human Drug User Fee
9 programs, with no over-allocation of user fees, and
10 that FDA is on a path to improve its policies,
11 procedures, and processes, as well as its technology
12 systems, to meet the increasing complexity within the
13 Human Drug User Fee program.

14 So, I think -- that's the key takeaway from
15 this, is that this is -- and it's a highly technical
16 evaluation term, but this is a good news story
17 overall.

18 We think that FDA, while they're fully
19 compliant, and obviously, you see today they're moving
20 forward trying to anticipate future problems and make
21 their selves more efficient, more effective, we think
22 that they are also well placed to take advantage of

1 some opportunities that we identified as part of this
2 process.

3 Here I'll focus on the opportunities, instead
4 of going through all the key -- all the takeaways.
5 We'll just look at the right side.

6 We found that FDA didn't really have a fully
7 integrated User Fee Management Policy and Procedures
8 framework, resulting in localized processes. The
9 resulting variation of practices leads to a lack of
10 standardization.

11 Bottomline is that we're recommending that
12 the FDA have procedures and policies that goes soup to
13 nuts, all the way throughout the whole organization,
14 so that you have more standardization.

15 In addition, centers and offices rely on
16 distributed tools and systems that require a manual
17 reconciliation and validation, which can lead to
18 process inefficiencies, and FDA is planning on
19 extending the central system to the centers and
20 offices.

21 Here it's good to note that -- I emphasize
22 that we took a snapshot of 2018, and what you're

1 looking at today is that this is a moving target.
2 That while we looked at things as of 2018, FDA was
3 continuing to improve in their system, and their
4 processes, so that they're already addressing some of
5 the concerns we identified.

6 And here we're talking about that there's a
7 lot of centralized systems that provide the
8 information that the FDA needs. We think that there's
9 still a lot of manual activity, a significant amount
10 of manual activity, at center level that could benefit
11 from similar technology and the FDA is looking to
12 address that.

13 Under administration of fee program
14 resources, we found that further efficiency gains can
15 be realized through center level automation, like
16 electronic billing for PDUFA and BsUFA, use of
17 automated workflow tools, and to streamline waiver and
18 exemption process, and we noted that efforts are
19 already underway to leverage existing FDA customer
20 service technologies to streamline customer service
21 and request processing for the three programs.

22 In terms of oversight and governance, we

1 thought that FDA would benefit from the creation of
2 high level strategic objectives that cut across all
3 the user fee programs and describe the plans to
4 achieve the negotiated individual program before those
5 commitments.

6 This would help user fee oversight bodies
7 align their investments to projects that achieve
8 optimal long term outcomes and performances.

9 Technical capability is really looking at the
10 staffing, and the capabilities of the staff that
11 implement these programs. Here we found that, based
12 on supervisors desired proficiency, the FDA and
13 financial management staff should increase proficiency
14 in decision support, problem solving, and analytical
15 skills, and improve training in financial and related
16 systems, and enhance organizational structure
17 knowledge.

18 Under the fifth category, user fee estimating
19 methodology, we thought that while the portfolio
20 performed well in FY2018 overall, that FDA could
21 improve the forecasting accuracy of individual fee
22 units, based on federal best practices for predictive

1 modeling.

2 We gave them some examples of that, and the
3 research alternative methodologies, quality data, and
4 policies with the help of stakeholders, and applied
5 methodological approaches, to leverage industry inputs,
6 external market data, and subject matter expert
7 opinions.

8 In conclusion, what I'd like to thank FDA for
9 all the cooperation. They asked for a very in-depth
10 review, and this goes along the category of be careful
11 what you ask for. We spent a year going through FDA's
12 financial management activities and estimating
13 methodologies. They made their staffs available on
14 multiple occasions.

15 We had a lot of spirited conversations, and
16 we had a lot of data requests that they constantly
17 were willing to fulfill, and so, we just really
18 appreciate all the cooperation. Thank you.

19 MR. TYLER: Well, good morning. We're going
20 to keep moving along. I'm Jay Tyler, I'm the Chief
21 Financial Officer here at FDA, and also the Head of
22 the Office of Finance, Budget and Acquisitions.

1 So, this morning I want to talk to you about
2 how FDA's going to address the findings from the Grant
3 Thornton MITRE study. We appreciate the
4 collaboration, as Jim said, very detailed approach to
5 this, and we worked very close with MITRE, as well as
6 the centers and offices, to identify all the areas
7 that we need to address.

8 So, I'm going to go through this focus area
9 by focus area; as Jim indicated, there were five focus
10 areas.

11 So, starting with focus area one, Resource
12 Planning Request and Allocation and User Fee
13 Administration Process. I think the key take away
14 here, for FDA, and what we're going to do to address
15 this area, and next steps, if you will, and the action
16 plan that we're going to put in place, we took to
17 heart very much, through these discussion, these
18 detailed discussions over the past year, that the
19 level of knowledge, in terms of how we administer
20 these user fees here at FDA, certainly varies.

21 The further that staff get away from, sort
22 of, the day to day administration of these fee

1 programs, the less knowledge, of course, that they
2 have, and we know that that's a gap that we need to
3 close.

4 There are many participants in these
5 programs, and we want everyone to have a level playing
6 field, in terms of their knowledge in how these
7 programs are administered.

8 And so, one of the things that we're going to
9 do, key things that we're going to do, with respect to
10 focus area one, is make sure, as Jim indicated, that
11 we have a soup to nuts policy and procedures
12 framework. Today I call it a playbook; we may call it
13 something else when we actually put this into play and
14 in action.

15 But we will have a comprehensive set of
16 policies and procedures that everyone in the Agency
17 will follow.

18 The folks in my office, and in some of the
19 more immediate sub-finance offices in the centers,
20 understand these programs thoroughly. But we don't
21 have a comprehensive set of policies and procedures
22 that everyone references, down to the person in a

1 center, if you will, that might interact once a month
2 with one of the fee programs.

3 So, we want to make sure, again, that
4 everyone's working from a level playing field.

5 We're also going to make sure that we have
6 better leverage of existing tools and processes, that
7 are available at the corporate offices. Meaning my
8 office, the Office of the Commissioner.

9 We believe we have some state of the art
10 tools, particularly, our Integrated Budget and
11 Acquisition Planning System that is probably pretty
12 unprecedented in the Federal Government. Meaning that
13 we can do payroll forecasting, we can do acquisition
14 planning, we county do budget formulation planning and
15 justification. We produce our budget justification,
16 click of a button; it's over 300 pages. And we, of
17 course, can do budget execution monitoring out funds.

18 Now, we have these tools at the corporate
19 level, but they haven't been deployed appropriately
20 into the sub-centers and offices in FDA, and this
21 study certainly pointed that out, and we're going to
22 be making sure that we're able to leverage that tool

1 across all of the centers and offices and be able to
2 implement, what we call, child (ph) applications of
3 our IBAP solution, Integrated Budget and Planning
4 System.

5 So, that's how we're going to address focus
6 area one.

7 For focus area two, the finding here was
8 that, again, the centers and offices should leverage
9 our tools and systems better, and so I've -- with
10 respect to how we're going to address focus area one,
11 I've already, sort of, identified what we intend to
12 do.

13 But we also want to broaden training
14 opportunities. My office offers corporate level
15 training in very financial management topics, anywhere
16 from the appropriation laws, to how to track resources
17 in our core financial system.

18 But we do need to develop a corporate level
19 offering, with respect to how we manage our user fee
20 programs here at FDA. And so, we're going to be
21 making sure that that's offered, but that also we
22 offer to our centers and offices more training on our

1 existing tools and processes, our core financial
2 system, which is a Oracle based federal financial
3 management system, our user fee collection system,
4 which is our accounts receivable system that
5 interfaces with the public for fee paying, and of
6 course industry, as well as the budgeting system that
7 I mentioned.

8 So, training and access to tools, more
9 general management training around our finances, as
10 well as training on leveraging the tools and systems
11 that we already have and putting those tools and
12 systems in place more locally in the centers and
13 offices, is how we're going to address focus area two.

14 For focus area three, oversight and
15 governance; took this area or finding to heart as
16 well. We've had a couple iterations of governance
17 here, with respect to how we administer our user fee
18 programs at FDA. We had a legacy User Fee Financial
19 Council. That council proved to be effective for the
20 time that it was in place, but during the tenure of
21 that council, we noticed that the council was very
22 much focused on the finances, and the financial

1 management of our user fee programs, but sometimes
2 there were gaps in the knowledge level of the members
3 of that council, with respect to strategic policy
4 direction and steering for our user fee programs.

5 So, we've reconstituted our user fee
6 governance, and now it's been retitled the User Fee
7 Financial Management Council, focused on the notion
8 that this council is focused on the financial
9 management of our user fee programs, that but that in
10 order to fill the gap around a policy direction for
11 our user fee programs, we need to leverage the top
12 leadership of the Agency to get that guidance and
13 direction.

14 And so, we are building a partnership with,
15 what we call here, the Executive Committee, that
16 consist of all of our center and officer directors, as
17 well as the FDA Commissioner, to make sure that at
18 least twice a year we engage with the Executive
19 Committee on topics in areas that we should
20 strategically be focusing on, in terms of the
21 direction of our user fee programs, and making sure
22 that there's alignment of how we allocate resources,

1 user fee resources, to the strategic direction that is
2 coming from the top leadership of the Agency.

3 So, for technical capabilities, the MITRE GT
4 Team essentially found that for our staff they have
5 the right skillsets, we're able to retain our
6 financial management team, in general. We don't have
7 a significant amount of attrition, but there is
8 certainly opportunity to increase their knowledge and
9 expertise around how we administer our fee programs,
10 as well as their general financial management
11 expertise.

12 So, we'll be building a greater
13 collaboration, as I already indicated, with my office
14 and with the budget and finance staffs in the centers
15 here at FDA, to make sure that they enhance their
16 skillsets. We'll be offering, as I've already
17 indicated, more training from the central
18 organization, as well as sharing our knowledge and
19 offering more training around our tools and our
20 processes and making sure that the existing corporate
21 tools are put in place in all of the centers and
22 offices.

1 Focus area five; I think Josh has already
2 covered this a bit, but the essence of this here is
3 that we do need to broaden our processes, our
4 methodologies, for how we predict our fees, or revenue
5 streams, with respect to the various human drug
6 programs, and particularly with respect to our newer
7 programs, and I think Josh and Andy have already
8 indicated the volatility with BsUFA.

9 And so, our hope is that with the advanced
10 predictive analytics that we'll be putting in place,
11 under the initiative for Modernized Time Reporting and
12 Resource Capacity Planning, that we will be able to
13 look forward, forecast better, versus looking
14 backward, in terms of being able to predict our fee
15 revenue streams.

16 So, we're very excited about continuing along
17 the path of Modernized Time Reporting, Resource
18 Capacity Planning, and we think that we will be able
19 to smooth out allowing the volatility that we're
20 seeing in -- particularly with BsUFA, as well even
21 further tightened what's already pretty close
22 estimation for -- in terms of the fee streams, for

1 PDUFA and GDUFA.

2 So, that's the essence of how we're going to
3 deal with the results from the User Fee Evaluation
4 Study for our finances. We have not received any
5 request for anyone to make any public comment, so we
6 are way ahead of schedule and we're going to end the
7 meeting.

8 We really thank you for your participation
9 today. We remind you that the public docket is open
10 until July 8th, so seeing as no comments are being
11 made in this forum, you're certainly encouraged to
12 provide any comments, as long as the docket is open.

13 So, again, thank you and we look forward to
14 seeing you next year.

15 (Whereupon, at 10:18 a.m. the meeting was
16 concluded.)

1 CERTIFICATE OF NOTARY PUBLIC

2 I, KeVon Congo, the officer before whom the
3 foregoing proceedings were taken, do hereby certify
4 that any witness(es) in the foregoing proceedings,
5 prior to testifying, were duly sworn; that the
6 proceedings were recorded by me and thereafter reduced
7 to typewriting by a qualified transcriptionist; that
8 said digital audio recording of said proceedings are a
9 true and accurate record to the best of my knowledge,
10 skills, and ability; that I am neither counsel for,
11 related to, nor employed by any of the parties to the
12 action in which this was taken; and, further, that I
13 am not a relative or employee of any counsel or
14 attorney employed by the parties hereto, nor
15 financially or otherwise interested in the outcome of
16 this action.

17
18 KeVon Congo

19 Notary Public in and for the

20 District of Columbia
21
22

CERTIFICATE OF TRANSCRIBER

I, Corinne Yanosy, do hereby certify that this transcript was prepared from the digital audio recording of the foregoing proceeding, that said transcript is a true and accurate record of the proceedings to the best of my knowledge, skills, and ability; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.



Corinne Yanosy

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